The following corrections or additions to the January 2003 list were published in the Federal Register in October 2003.

New Approvals

NADA Number: 141-209

Trade Name:	Naxcel® XT
Ingredients:	Ceftiofur crystalline free acid
Sponsor:	Pharmacia & Upjohn Company
Approval Date:	September 5, 2003
Status:	Prescription only
Route:	Subcutaneous (ear)
Species:	Cattle (beef and nonlactating dairy)
Drug Form:	Liquid (suspension)
Concentration:	200 milligrams per milliliter
Indications:	For the treatment and control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, P. multocida,* and *H. somnus*.
Tolerance:	21CFR 556.113 Ceftiofur: Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible tissue at 8 parts per million in kidney (target tissue), 2 parts per million in the liver, 1 part per million in muscle, 100 parts per billion in milk, and 166 parts per million for the injection site.
Withdrawal:	Zero days
Patent Number:	5,721,359 Expiration date: February 24, 2015
Exclusivity:	3 years

21CFR 522.315 & 556.113

NADA Number: 141-222

Trade Name:	Matrix™
Ingredients:	Altrenogest
Sponsor:	Intervet, Inc.
Approval Date:	September 30, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Swine (sexually mature gilts)
Drug Form:	Liquid (solution)
Concentration:	2.2 milligrams per milliliter
Indications:	For synchronization of estrus in sexually mature gilts that have had at least one estrous cycle.
Tolerance:	21CFR 556.36 Altrenogest: Tolerances for residues of altrenogest are established as follows: 4 parts per billion in liver (target tissue) and 1 part per billion in muscle. The acceptable daily intake (ADI) for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.
Withdrawal:	21 days
Patent Number:	5,214,035 Expiration date: April 16, 2012
Exclusivity:	3 years

21CFR 520.48 & 556.36

ANADA Number: 200-265

Pioneer Product:	111-798
Trade Name:	Praziquantel Tablets
Ingredients:	Praziquantel
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	August 28, 2003
Status:	Prescription only
Route:	Oral
Species:	Dogs and puppies
Drug Form:	Tablet
Concentration:	34 milligrams per tablet
Indications:	For the removal of *Dipylidium caninum, Taenia pisiformis, Echinococcus granulosus* and for the removal and control of *Echinococcus multicularis*.

21CFR 520.1870

ANADA Number: 200-324

Pioneer Product:	012-559
Trade Name:	Dexamethasone Injection
Ingredients:	Dexamethasone
Sponsor:	Veterinary Laboratories, Inc.
Approval Date:	August 19, 2003
Status:	Prescription only
Route:	Intravenous, intramuscular
Species:	Horses, cattle
Drug Form:	Liquid (solution)
Concentration:	2 milligrams per milliliter
Indications:	For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses.

21CFR 522.540

Supplemental Approvals

NADA Number: 140-872

This supplemental application provides for revised wording of the indication and precautionary labeling.

Trade Name:	Posilac®		
Ingredients:	Sometribove zinc		
Sponsor:	Monsanto Company		
Approval Date:	September 11, 2003		
Status:	Over-the-counter		
Route:	Subcutaneous		
Species:	Cattle (lactating dairy)		
Drug Form:	Liquid (suspension)		
Concentration:	500 mg per syringe		
Indications:	To increase production of marketable milk in healthy lactating dairy cows.		
Tolerance:	None		
Withdrawal:	Meat and milk - zero days		
Patent Number:	4,985,404	Expiration date:	January 15, 2008
	5,013,713		May 7, 2008
	5,086,041		February 4, 2009
	5,411,951		February 4, 2009
	5,474,980		February 4, 2009
	5,595,971		February 4, 2009
	5,739,108		February 4, 2009

21CFR 522.2112 & 510.600

NADA Number: 141-200

This supplemental application provides for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

Trade Name:	EAZI-Breed™ CIDR® Cattle Insert
Ingredients:	Progesterone
Sponsor:	Pharmacia & Upjohn Company
Approval Date:	July 29, 2003
Status:	Over-the-counter
Route:	Intravaginal
Species:	Cattle (lactating dairy)
Drug Form:	Insert
Concentration:	1.38 milligrams per insert
Indications:	For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.
Tolerance:	21CFR 556.540 Progesterone: Not established.
Withdrawal:	Milk - zero days Meat – 21 days
Exclusivity:	3 years

21CFR 529.1940

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor

NADA Number: 046-780, 096-671, 096-672, 098-288, 099-604, 099-605, 099-606, 099-607, 118-550, 119-141, 138-405, 140-583, 200-115

From: Anthony Products. Co.
To: Cross Vetpharm Ltd.
Broomhill Rd.,
Tallaght, Dublin 24, Ireland
Drug labeler code: 061623

Change of Sponsor's Drug Labeler Code

Monsanto Company
From: 059945
To: 000911

Removal of a Patent Number

NADA Number: 141-221

Patent Number: 4,734,437 Expiration Date: September 1, 2004

Addition of a Patent Number

NADA Number: 140-863

Patent Number: 5,643,967 Expiration Date: July 1, 2014

NADA Number: 141-172

Patent Number:	Expiration Date:
4,690,951	September 1, 2007
4,734,437	September 1, 2004
5,643,967	July 1, 2014
5,631,298	May 20, 2014

Extension of a Patent Expiration Date

NADA Number: 140-863, 141-221

Patent Number: 4,690,951 Expiration Date: September 1, 2007

Actions Taken by FDA Center for Veterinary Medicine

Suitability Petition Action

Number:	03P-0469/CP1
Sponsor:	Eugene G. Keller
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will have a different strength and dosage form from the pioneer.
Action:	Filed on October 8, 2003.

Correction to the January 1, 2003 list of the Green Book

The Food and Drug Administration (FDA) is correcting a notice of opportunity for hearing that published in the Federal Register on August 8, 2003 (68 FR 47332) (Green Book, September 15, 2003 monthly update, page 8.50). FDA is correcting a product name used by the current sponsor of NADA 141-137 to Pennitracin MD 50 Type A Medicated Article, the FR citation for a Drug Efficacy Study Implementation Program finding of effectiveness, and the column headings of six tables. These corrections are being made to improve the accuracy of the Federal Register. This notice also extends the deadline for parties who have requested a hearing to submit data and analysis upon which their request for a hearing relies. Other interested persons may submit comments on the notice of opportunity for hearing (NOOH) before the deadline. Submit all written data and analysis upon which a request for a hearing relies and other written comments by November 6, 2003.